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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,003	08/18/2003	Zhongming Zeng	02291/100H204-US1	2972
7278	7590	02/08/2005	EXAMINER	
DARBY & DARBY P.C.			PESELEV, ELLI	
P. O. BOX 5257			ART UNIT	
NEW YORK, NY 10150-5257			PAPER NUMBER	

1623

DATE MAILED: 02/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/643,003

Applicant(s)

ZENG, ZHONGMING

Examiner

Elli Peselev

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 6-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 6-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4 and 6-13 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lamothe et al (U.S. Patent No. 5,518,733).

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Lamothe et al disclose a composition useful for the development of beneficial vaginal microflora and the preservation of acidic conditions (column 3, lines 15-16) comprising maltose and other fructo-oligosaccharides (column 2, lines 8-22) in an amount of 0.1 to 20% by weight of said composition (column 6, lines 41-44), less than 1% by weight of a preserving agent having an antifungal action (column 3, lines 29-34) and an acidic buffer which adjusts the pH of the composition to the range of 5 to 7. Lamothe et al further disclose a method for favoring the development of bacilli (column 6, lines 8-52). The claimed compositions and methods are anticipated from Lamothe et al. In addition, if there are any differences between the claimed compositions and methods and the prior art's compositions and methods, the differences would appear to be minor in nature and the claimed compositions and methods which fall within the scope of the prior art's disclosure, would have been prima facie obvious to a person having ordinary skill in the art at the time the instant invention was made.

Applicant's arguments filed December 3, 2004 have been considered but have not been found persuasive.

Applicant contends that Lamothe et al disclose a cosmetic composition containing maltose can promote the growth of some microorganisms in the vagina but do not disclose said composition to be useful for treating any diseases but was said to be for promoting Gram-positive cocci. Applicant contends that the prior art presented teaches that said bacteria are never beneficial when found in the vagina. These arguments and the prior art presented have been considered but have not been found persuasive. Claims 1-4 and 6-10 are directed to compositions. In response to

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applicant's argument that Lamothe et al do not disclose the intended use, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963).

With respect to method claims 11-13, note that the instant claims are directed to a method of treating a patient suffering from conditions such as vaginitis, a disturbance of vaginal bacterial flora or bacterial vaginosis, wherein said conditions are accompanied with a reduction of the number of Gram-positive bacilli. Since Lamothe et al disclose a method of favoring the development of Gram-positive bacilli in vagina, a person having ordinary skill in the art would have envisaged using the method disclosed by Lamothe et al for treating conditions of the vagina which are in need of promoting the development of Gram positive bacilli. Applicant's argument that the bacteria disclosed by Lamothe et al are never beneficial in vagina is not understood since the instant claims read on promoting the growth of the same bacteria.

Applicant also contends that experimental examples 1 and 2 on pages 33-40 show that the composition claimed therein has unexpected properties. Said argument has not been found persuasive since the composition disclosed by Lamothe et al is the

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same as the claimed composition and would be expected to possess the same unexpected properties.

Claims 1-4 and 6-13 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Cohen et al (U.S. Patent No. 6,165,997).

Cohen et al disclose in the Abstract a pharmaceutical formulation for stimulating growth of Gram-positive Bacilli and increasing the acidity in vagina comprising sucrose and/or maltose, optionally with other sugars, viscous base and anti-fungal agents. The claimed compositions and methods are anticipated by Cohen et al. In addition, if there are any differences in the amounts of the agents used, it would have been within routine experimentation by a person having ordinary skill in the art at the time the instant invention was made to determine optimal percentages of the agents in the reference's composition.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 9.00-5.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elli Peseelev

elli kesh
ELLI PESELEV
PRIMARY EXAMINER
GROUP 1200